

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

In the present Amendment, claim 1 has been amended and claims 2-27 have been canceled without prejudice or disclaimer of the subject matter contained therein. Also, claims 28-47 have been added. Thus, claims 1 and 28-47 are pending in the present application.

No new matter has been added by way of the amendment and new claims. The amendment to claim 1 incorporates the subject matter from canceled claims 2 and 7-9. New claims 28-47 correspond to canceled claims 3-6, 10-15, 17-19 and 21-27, respectively. Also, new, independent claim 38 incorporates subject matter from canceled claim 20.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 112, Second Paragraph

Claim 20 stands stand rejected under 35 U.S.C. § 112, second paragraph, for asserted lack of definiteness (see paragraphs 2-3, page 2 of the Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested.

The subject matter of claim 20 now appears in new claim 38. Applicants respectfully refer the Examiner to claim 38 as shown herein, wherein "a" is recited instead of "the" before "pore depth" and "pore diameter." Reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. § 102(b)

Claims 1-4, 14-19, 24, 25 and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by **Branemark *et al.*** '891 (U.S. Patent No. 4,330,891) (see paragraphs 4-5 of the Office Action). Applicants respectfully traverse and reconsideration is based on the following remarks.

Method claim 1 and the claims dependent thereon

As amended, instantly pending claim 1 specifies that the implant surface is a metallic implant surface and that the desired microroughness is provided by treating the metallic implant surface with an aqueous solution of hydrofluoric acid, resulting in an etching process, wherein the concentration of the hydrofluoric acid is less than 0.5 M. In order to obtain a surface roughness comprising pores and peaks having a diameter of $\leq 1 \mu\text{m}$, and a pore depth of $\leq 500 \text{ nm}$, which has been shown to give surprisingly good biocompatibility results (see paragraph [0027] of the published application U.S. 2006/0154206 A1), the metallic implant surface should be treated with an aqueous solution of HF such that etching occurs, and the HF concentration should be less than 0.5 M.

In contrast to the present invention, the cited Branemark '891 reference fails to disclose any treatment with HF and does not mention that the treatment comprises etching. Accordingly, amended claim 1 is not anticipated by Branemark '891. Anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949 (Fed. Cir. 1990) (citing *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Thus, because of the lack of disclosure of all features as instantly claimed, the rejection in view of Branemark '891 has been overcome. By virtue of their dependency on amended claim 1, the rejection of the other claims (now in the form of new claims) has also been overcome.

Product claim 38 and the claims dependent thereon

Regarding instantly pending claim 38 (formerly claim 17), the following microroughness parameters are recited:

- (1) a pore diameter of $\leq 1 \mu\text{m}$;
- (2) a pore depth of $\leq 500 \text{ nm}$; and
- (3) a peak width, at half the pore depth, of from 15 to 150% of the pore diameter.

It has been shown that surprisingly good biocompatibility results are obtained for an implant, implanted into bone tissue are achieved with an implant having the above mentioned microroughness parameters. Both an improved rate of attachment and a stronger bond between the implant surface and the bone tissue are obtained. Thus, the fine microroughness improves the osseointegration process (see paragraph [0027] of the published '206 application).

The cited Branemark '891 reference discloses an implant having a micro-pitted surface, wherein the diameter of the pits is in the range of from 10 nm to 1000 nm. Hence, Branemark '891 discloses a microroughness which arguably corresponds to (1) above, but fails to disclose the parameters (2) and (3). In other words, Branemark '891 fails to disclose all claimed features and this rejection has been overcome. *In re Robertson; supra*. Accordingly, Branemark '891 does not anticipate claim 38 and any claim dependent thereon. Withdrawal of this rejection is respectfully requested.

Issues under 35 U.S.C. § 103(a)

Claims 5, 6, 8-13, 20-23 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Branemark '891** in view of **Ellingsen et al.** (WO 95/17217) (see paragraphs 6-7 of the Office Action). Applicants respectfully traverse and reconsideration is based on the following remarks. Overall, Applicants do not concede that a *prima facie* case of obviousness has been established.

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness,

wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Here, the Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue, and the rationale in combining the cited references is improper.

The method claims

Claim 5 is now shown as new claim 30, wherein new claim 30 depends on claim 1. Similar changes are made with respect to the other disputed claims. As presently amended, claim 1 includes the features of now cancelled claims 2 and 7-9. More specifically, the present invention is directed to an implant surface that is a metallic implant surface, and the desired microroughness is provided by treating the metallic implant surface with an aqueous solution of hydrofluoric acid, resulting in an etching process, wherein the concentration of the hydrofluoric acid is less than 0.5 M. The disputed claims add some additional feature of claim 1. For instance, claim 30 further recites that the invention has an average atomic concentration of at least 0.2 at% fluorine and/or fluoride. According to the Examiner, it would have been obvious to the skilled person to modify the method of Branemark '891 with the steps of Ellingsen *et al.* Applicants respectfully disagree.

Branemark '891 neither discloses treatment with HF nor etching, and Ellingsen *et al.* fails to account for such deficiencies of the primary reference. Although Ellingsen *et al.* teaches a method for treating an implant surface with an aqueous solution of hydrofluoric acid, this

method does not result in any significant etching of the implant surface (see Ellingsen *et al.* at page 8, lines 1-3). Applicants note at least pending claim 1 as shown herein.

It should be noted that before the etching starts, the oxide layer provided on the implant surface is removed by the hydrofluoric acid, and it is not until the acid gets in contact with the implant surface that the etching process starts (see paragraph [0086]). In Ellingsen *et al.*, the implant is immersed into a treatment solution comprising hydrofluoric acid. This treatment results in the removal of the oxide layer, but it does not result in any etching, and an implant of Branemark '891, treated with the method of Ellingsen *et al.*, will not have the same surface characteristics as the inventive implant. One of ordinary skill in the art has no reason, rationale or incentive to use another surface treatment. The present invention would not even be achieved based on Branemark '891 and Ellingsen *et al.*

Further, Applicants note that etching is critical in order to obtain the desired microroughness, i.e., a microroughness comprising pores and peaks having a pore diameter of $\leq 1 \mu\text{m}$, and a pore depth of $\leq 500 \text{ nm}$. Applicants also describe in the background description of the present application (see paragraph [0015] of US '206) that the treatment with HF of Ellingsen *et al.* results in an implant surface which is unaffected and wherein no significant etching occurs. In contrast, in the present invention, the metallic implant surface should be treated with an aqueous solution of HF such that etching occurs, and the HF concentration should be less than 0.5 M. The concentration of HF (aq) determines the ratio between etched areas; i.e. areas having a microroughness, and non-etched areas (see also paragraph [0089] of the published US '206 application).

Hence, it cannot be considered obvious for a skilled person to provide an implant with the specific surface roughness as specified in amended claim 1, by treating the implant surface with an aqueous solution of hydrofluoric acid, resulting in an etching process, wherein the concentration of the hydrofluoric acid is less than 0.5 M. The references have been improperly combined.

Accordingly, a proper weighing of the *Graham* factors lies in Applicants' favor. The Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue, and the rationale in combining the cited references is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Implant claim 38 and the claims dependent thereon

Regarding pending claim 38, this claim specifies that the implant surface is metallic and that the microroughness comprises peaks having a peak width, at half the pore depth, of from 15 to 150% of the pore diameter. The present inventors have shown that surprisingly good biocompatibility results are obtained for the implant when implanted into bone tissue having the above mentioned microroughness. Both an improved rate of attachment, and a stronger bond between the implant surface and the bone tissue, are obtained. Thus, the fine microroughness improves the osseointegration process (see paragraph [0027] of US '206).

Branemark '891 discloses an implant having a micro-pitted surface. The only description given to this surface is that the pits have a diameter in the range of from 10 nm to 1000 nm. Ellingsen *et al.* does not account for the deficiencies of Branemark '891.

Specifically, Ellingsen *et al.* fails to disclose any microroughness parameters, and the improved biocompatibility of the disclosed implant is thought to be due to fluoride being retained on the surface of the implant (Ellingsen *et al.*, see page 7, lines 17-19). The implant of Ellingsen *et al.* is unaffected by the proposed HF treatment, and this is also supported in Figure 2 and discussed on page 15, lines 4-8 of Ellingsen *et al.*

Accordingly, a proper weighing of the *Graham* factors lies in Applicants' favor. The Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue, and the rationale in combining the cited references is improper. Also, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *see also* MPEP § 2143.03. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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